UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY

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MONOSOL RX, LLC,)
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Plaintiff,)
v.) Civil Action No
BIODELIVERY SCIENCES) COMPLAINT FOR PATENT
INTERNATIONAL, INC.,) INFRINGEMENT AND DEMAND) FOR JURY TRIAL
MEDA PHARMACEUTICALS INC.,)
and)
)
AVEVA DRUG DELIVERY SYSTEMS, INC.,)
)
)
Defendants.)
)

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Counsel for Plaintiff MonoSol Rx, LLC

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff MonoSol Rx, LLC, by its attorneys, hereby alleges as follows:

PARTIES

- 1. Plaintiff MonoSol Rx, LLC ("MonoSol") is a limited liability company organized and existing under the laws of the State of New Jersey, with its principal place of business at 30 Technology Drive, Warren, New Jersey 07059. MonoSol specializes in the development and commercialization of film pharmaceutical and over-the-counter drug products.
- 2. Defendant BioDelivery Sciences International, Inc. ("BDSI") is a corporation organized and existing under the laws of the State of North Carolina, with its principal place of business at 801 Corporate Center Drive, Suite 210, Raleigh, North Carolina 27607.
- 3. Defendant MEDA Pharmaceuticals Inc. ("MEDA") is a corporation organized and existing under the laws of the State of New Jersey, with its principal place of business at 265 Davidson Ave., Suite 300, Somerset, New Jersey 08873.
- 4. Defendant Aveva Drug Delivery Systems, Inc. ("Aveva") is a corporation organized and existing under the laws of the State of Florida, with its principal place of business at 3250 Commerce Parkway, Miramar, Florida 33025.

NATURE OF THE ACTION

5. This is an action for the infringement of United States Patent No. 7,824,588 ("the '588 patent").

JURISDICTION AND VENUE

- 6. This action arises under the patent laws of the United States (35 U.S.C. §§ 1 *et seq.*). This court has jurisdiction over the subject-matter pursuant to 28 U.S.C. §§ 1331 and 1338(a).
- 7. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 (b) and (c) and 1400(b).

- 8. BDSI is subject to personal jurisdiction in New Jersey because BDSI has purposely availed itself of the privileges of conducting business there by reaching out and transacting business with MEDA, a New Jersey corporation, in connection with the allegations in this Complaint. For instance, BDSI has licensed the marketing of the OnsolisTM film products to MEDA.
- 9. MEDA is subject to personal jurisdiction in New Jersey because MEDA is a New Jersey corporation. In addition, MEDA has purposely availed itself of the privileges of conducting business in New Jersey by directing activities there in connection with the allegations in this Complaint. For instance, MEDA has directed the manufacture, sale, and distribution of the accused OnsolisTM film products from New Jersey.
- 10. Aveva is subject to personal jurisdiction in New Jersey because Aveva has purposely availed itself of the privileges of conducting business there by reaching out and transacting business with MEDA, a New Jersey corporation, in connection with the allegations in this Complaint. For instance, Aveva has manufactured the OnsolisTM film products at the direction of MEDA.

THE PATENT

11. On November 2, 2010, the '588 patent entitled "Method of Making Self-Supporting Therapeutic Active-Containing Film" was duly and legally issued to inventors Robert K. Yang, Richard C. Fuisz, Garry L. Myers, and Joseph M. Fuisz, and assigned to MonoSol. MonoSol owns all rights, title, and interest to the '588 patent, including the right to sue and to recover for any current or past infringement of that patent. A copy of the '588 patent is attached as Exhibit A.

ACTS GIVING RISE TO THIS ACTION

- 12. BDSI, MEDA, and Aveva (collectively, "Defendants") make, use, offer to sell, and/or sell certain pharmaceutical films under the OnsolisTM name. The accused OnsolisTM film products are manufactured in a manner that infringes one or more claims of the '588 patent.
- 13. Aveva manufactures the Onsolis[™] film products, and MEDA markets the Onsolis[™] film products, both under license from BDSI. The Onsolis[™] film products are sold to distributors, retailers, and/or customers who resell and/or use the Onsolis[™] film products throughout the United States, including in the State of New Jersey.
- 14. Defendants do not have a license or other authority to practice the inventions claimed in the '588 patent.

INFRINGEMENT OF THE '588 PATENT

COUNT I

- 15. MonoSol incorporates each of the preceding paragraphs 1-14 as if fully set forth herein.
- 16. On information and belief, MEDA and Aveva have been, and currently are, directly infringing one or more claims of the '588 patent, in violation of 35 U.S.C. § 271(a), by making, using, offering to sell, and/or selling the OnsolisTM film products.
- MEDA and Aveva have had constructive notice of the '588 patent pursuant to 35U.S.C. § 287(a).
- 18. As a result of MEDA and Aveva's infringing activities, MonoSol has suffered and will continue to suffer irreparable injury, unless MEDA and Aveva are permanently enjoined by this Court from infringing the claims of the '588 patent.

19. As a result of MEDA and Aveva's infringement of one or more claims of the '588 patent, MonoSol has suffered damages.

COUNT II

- 20. MonoSol incorporates each of the preceding paragraphs 1-14 as if fully set forth therein.
- 21. On information and belief, BDSI has been, and currently is, inducing the infringement of one or more claims of the '588 patent, in violation of 35 U.S.C. § 271(b),
- 22. On information and belief, BDSI actively induces the infringement of one or more claims of the '588 patent by Defendants MEDA and Aveva, with specific intent that the '588 patent be infringed and/or deliberate indifference to a known risk of such infringement.
- 23. BDSI has had constructive notice of the '588 patent pursuant to 35 U.S.C. § 287(a).
 - 24. On information and belief, BDSI's infringement of the '588 patent is willful.
- 25. As a result of BDSI's infringing activities, MonoSol has suffered and will continue to suffer irreparable injury, unless BDSI is permanently enjoined by this Court from infringing the claims of the '588 patent.
- 26. As a result of BDSI's infringement of one or more claims of the '588 patent, MonoSol has suffered damages.

DEMAND FOR JUDGMENT

WHEREFORE, MonoSol requests the following relief:

1. A judgment that MEDA's and Aveva's making, using, offering to sell, and/or selling, within the State of New Jersey and elsewhere in the United States, the accused OnsolisTM film products infringes one or more claims of the '588 patent, in violation of 35 U.S.C. § 271(a);

- 2. A judgment that BDSI has actively induced others to infringe one or more claims of the '588 patent, in violation of 35 U.S.C. § 271(b);
 - 3. A judgment that BDSI has willfully infringed the '588 patent;
- 4. An award of damages adequate to compensate for Defendants' infringement of the '588 patent claims under 35 U.S.C. § 284, together with interest and costs as fixed by the Court;
- 5. An award of enhanced damages against BDSI for the willful infringement of the '588 patent;
- 6. A determination that this is an exceptional case within the meaning of 35 U.S.C. § 285, and an award of MonoSol's reasonable attorneys' fees;
- 7. An injunction, pursuant to 35 U.S.C. § 283, permanently prohibiting Defendants from infringing any claims of the '588 patent prior to the expiration of that patent, including any extensions;
 - 8. Such other costs and further relief as the Court deems just and proper.

JURY DEMAND

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, MonoSol requests a trial by jury on all triable issues.

Respectfully submitted,

s/ John A. Fedun

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November 2, 2010

CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Pursuant to Local Civil rule 11.2, counsel for Plaintiff MonoSol hereby certifies, to the

best of his knowledge, that the matter in controversy is not the subject of any other action

currently pending in any court, or of any pending arbitration or administrative proceeding.

CERTIFICATION PURSUANT TO L. CIV. R. 201.1

Pursuant to Local Civil rule 201.1, counsel for Plaintiff MonoSol hereby certifies that this

action is excluded from compulsory arbitration because, inter alia, it is based on an alleged

violation of a right secured by the Constitution of the United States; it involves complex legal

issues that predominate over the factual issues; and/or plaintiff seeks permanent injunctive relief.

s/ John A. Fedun

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Dated: November 2, 2010

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